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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,751

Applicant(s)

CHARNE ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-15, drawn to a plant cell of a *Brassica napus* plant having and “R” rating for blackleg and resistance to at least one AHAS-inhibitor herbicide wherein said plant is designated variety NS3213 represented by ATCC Accession No. PTA-2471, a plant and plant part and methods of using said cell, plant and plant part to produce a *Brassica* plant, classified in class 435, subclass 418, for example.
 - II. Claims 16 and 17, drawn to a method for preparing oil and/or meal from seed of a *Brassica* plant, classified in class 426, subclass 489, for example.
 - III. Claims 18 and 19, drawn to vegetable oil comprising all or part of a plant cell of a *Brassica* plant, classified in class 426, subclass 601, for example.
 - IV. Claims 20 and 21, drawn to meal produced using a seed of a *Brassica* plant, classified in class 426, subclass 615, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the *Brassica* plant part, the

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seed, of Group I can be used to practice a materially different process than the method of preparing oil and/or meal of Group II, such as the method of breeding a *Brassica* line encompassed by Group I.

3. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the *Brassica* plant, plant cell or plant part of Group I can be used for plant breeding. The subcombination has separate utility such as cooking oil.

4. Inventions I and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the *Brassica* plant, plant cell or plant part of Group I can be used for plant breeding. The subcombination has separate utility such as an animal feed.

5. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

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that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the vegetable oil of Group III can be made using a materially different process than that of Group II, such as blending oils from different *Brassica* plants.

6. Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the meal of Group IV can be made using a materially different process than that of Group II, such as a process wherein the oil is not separated.

7. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the vegetable oil of Group III and the meal of Group IV are compositionally distinct.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and because the search required for one of the groups is not required for another, restriction for examination purposes as indicated is proper.

9. During a telephone conversation with David Ran on 23 July 2003 a provisional election was made without traverse to prosecute the invention of Group I, claim 1-15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-21 are withdrawn from further consideration by the examiner, 37 CFR § 1.142(b), as being drawn to a non-elected invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Priority

11. Acknowledgment is made of Applicant's claim for foreign priority based on an application filed in Canada on 17 November 2000. It is noted, however, that applicant has not filed a certified copy of the 2,326,285 application as required by 35 U.S.C. § 119(b).

Specification

12. The disclosure is objected to because of the following informalities: At page 25, line 12 there is a closing bracket and at line 10 there is a parenthesis. This appears to be a typographical error.

Appropriate correction is required.

Claim Objections

13. Claims 5, 6 and 8 objected to because of the following informalities:

Claim 5 is in improper Markush format, at line 2, "a group" should be -- the group --, and at line 3 "or vegetative parts," should be -- and vegetative parts --, particularly to distinguish that "whether mature or embryonic" is directed to vegetative parts.

At claim 6, line 3, the phrase "to regenerate the" should read -- to regenerate a --.

At claim 8, line 1, the phrase "from a" should read -- from the -- for proper Markush format.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

15. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74

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(Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation vegetative parts, and the claim also recites roots and leaves, which is the narrower statement of the range/limitation.

16. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 7-11 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a method of breeding a *Brassica* line comprising crossing the exemplified NS2313 line with a second *Brassica* plant. At claim 8, the method of breeding is further defined as selected from method such as pedigree breeding and backcrossing.

Applicant describes *Brassica* line NS2313 that exhibits an "R" rating for blackleg and resistance to at least one AHAS-inhibitor.

Applicant does not describe the genus of progeny plants descendent from NS2313 that would be required to practice the claimed method of breeding as broadly claimed.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

18. Claims 7-11 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of making an F1 hybrid comprising crossing the *Brassica* plant designated NS3213 with another *Brassica* plant, does not reasonably provide enablement for any method of breeding a *Brassica* line using the *Brassica* plant designated NS3213 or progeny produced from said NS2313 variety. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a method of breeding a *Brassica* line comprising crossing the exemplified NS2313 line with a second *Brassica* plant. At claim 8, the method of breeding is further defined as selected from method such as pedigree breeding and backcrossing.

Applicant teaches *Brassica* line NS2313 that exhibits an "R" rating for blackleg and resistance to at least one AHAS-inhibitor.

Applicant does not teach the genus of progeny plants descendent from NS2313 that would be required to practice the claimed method of breeding as broadly claimed.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of

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working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant provides limited guidance for how to make and use progeny plants produced from the exemplified NS2313 *Brassica* in methods of breeding as broadly claimed. Applicant states that it is particularly difficult to develop varieties having IMI resistance in combination with other desirable traits because the inheritance of the IMI resistance trait is relatively complex (page 3, lines 2-4 of the specification). Hence, it would have required undue trial and error experimentation to make and use the myriad of progeny plants produced from the exemplified NS2313 *Brassica* in methods of breeding.

19. Claims 1-15 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that

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applicants have deposited the plant but there is no indication in the specification as to public availability on page 32 of the specification.

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent., would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

- (iv) a test of the viability of the biological material at the time of deposit
(see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

Conclusion

20. The claims are free of the prior art which neither teaches nor suggests the *Brassica* plant designated NS3213 or methods of using said plant by crossing with another *Brassica* plant.
21. No claims are allowed.
22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
28 July 2003